

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
Reregistration (under FIFRA, as amended)

EPA Reg. Number: 524-613
Date of Issuance: FEB 20 2014

Term of Issuance: Unconditional

Name of Pesticide Product: COT102 x MON 15985
Insect-Protected Cotton

Name and Address of Registrant (include ZIP Code):

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act.

The registration application referred to above, submitted in connection with registration under § 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you comply with the following terms.

- 1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Change the EPA Registration Number entry to "524-613" on the final printed label.

Signature of Approving Official: [Signature]
Robert McNally, Director
Biopesticides and Pollution Prevention Division (7511P)

Date: 2/20/14

EPA Form 8570-6

CONCURRENCES

Table with 4 columns and 3 rows (SYMBOL, SURNAME, DATE) containing handwritten entries for Reynolds, New, and McNally.

The following terms apply:

### **I. Gene Flow**

The following information regarding commercial production must be included in the grower guide for COT102 x MON 15985 and is a term of this registration:

- a) No planting of COT102 x MON 15985 is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of COT102 x MON 15985 is prohibited in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

The following information regarding test plots and seed production must occur on bags of COT102 x MON 15985 intended for these purposes and is a term of this registration.

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of *Bt* cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

### **II. Insect Resistance Management**

The required IRM program for COT102 x MON 15985 *Bt* cotton must have the following elements:

- Requirements relating to creation of a non-*Bt* cotton refuge in conjunction with the planting of any acreage of COT102 x MON 15985 *Bt* cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- Requirements for Monsanto Company to prepare and require COT102 x MON 15985 *Bt* cotton users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- Requirements for Monsanto Company to develop, implement, and report to EPA on programs to educate growers about IRM requirements;

- Requirements for Monsanto Company to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- Requirements for Monsanto Company to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1Ac, Cry2Ab2 and VIP3Aa19 proteins in the target insects;
- Requirements for Monsanto Company to develop, and if triggered, to implement a "remedial action plan" which would contain measures Monsanto Company would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- Annual reports on or before January 31<sup>st</sup> each year, except as indicated in the sections below.

a. Refuge Requirements for Pink Bollworm Resistance Management only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler

All growers of COT102 x MON 15985 must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) are planted for every 95 acres of COT102 x MON 15985 (total of 100 acres). The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. At the pre-squaring cotton stage only, the refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lb of active ingredient per acre). The variety of cotton planted in the refuge must be comparable to COT102 x MON 15985, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to COT102 x MON 15985. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the COT102 x MON 15985 fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton (refuge cotton) are planted for every 80 acres of COT102 x MON 15985 (total of 100 acres). The variety of cotton planted in the refuge must be comparable to COT102 x MON 15985 especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to COT102 x MON 15985. The non-

*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Bt* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the COT102 x MON 15985 cotton fields.

3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of COT102 x MON 15985. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Bt* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the COT102 x MON 15985 cotton. There is no field unit option.

b. Natural Refuge Requirements for Tobacco Budworm and Cotton Bollworm Resistance Management only in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas (excluding the following counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler), and Virginia (natural refuge refers to weeds, wild hosts or other cultivated crops that serve as sources of susceptible insects to mitigate any potential resistant insects arising from the *Bt* crops)

- 1) Monsanto Company must submit data to EPA by January 31<sup>st</sup>, 2017, and every five years thereafter, to support an EPA reassessment of the natural refuge and to confirm its effectiveness with tobacco budworm and cotton bollworm. The data must include: resistance monitoring data, cropping pattern analysis, and simulation modeling to reexamine levels of effective refuge in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Both cropping and land use patterns can change over time, which could impact the amount of natural refuge available to tobacco budworm and cotton bollworm relative to cotton. If based on this reassessment, EPA determines that additional tobacco budworm and/or cotton bollworm sampling, gossypol analysis, statistical analysis, and simulation modeling are needed to justify continuation of the natural refuge, Monsanto Company must submit these data within the EPA requested timeframe. If EPA's assessment concludes that the natural refuge is no longer scientifically supported, Monsanto Company agrees to submit an application to amend the registration to restore the structured refuge requirements previously required for tobacco budworm and cotton bollworm uses.
- 2) It is recommended that Monsanto Company develop a more complex, spatial model of resistance for COT102 x MON 15985 cotton that further considers the evolution of resistance "hotspots" (i.e. localized areas of resistance) and provide EPA with this information. Key issues like spatial structure, linkage disequilibrium, and differential movement of males and females have not yet been explored in detail for pyramided *Bt* proteins. Such models would be more desirable to examine the resistance evolution at the local level where natural refuge may be limited for one or more generations of

tobacco budworm.

c. Grower Agreements

While Monsanto Company will have flexibility to design its program to fit its own business practices, Monsanto Company must meet the following requirements.

- 1) Persons purchasing the COT102 x MON 15985 cotton product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto Company must continue to implement a system which is reasonably likely to assure that persons purchasing the COT102 x MON 15985 cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Monsanto Company must continue to use an approved grower agreement. If Monsanto Company wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto Company must submit to EPA the text of such changes to ensure the agreement is consistent with the terms of this registration.
- 5) Monsanto Company must continue an approved system which is reasonably likely to assure that persons purchasing the COT102 x MON 15985 cotton sign grower agreement(s).
- 6) Monsanto Company shall maintain records of all COT102 x MON 15985 cotton grower agreements for a period of three years from December 31 of the year in which the agreement was signed.
- 7) Monsanto Company must maintain records detailing the number of units of the COT102 x MON 15985 cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. Monsanto Company must submit the records to EPA upon request.
- 8) Monsanto Company must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

d. IRM Education and IRM Compliance Monitoring Programs

Monsanto Company's existing IRM education and compliance monitoring programs must be amended to include COT102 x MON 15985 and address the following elements:

- 1) Monsanto Company must design and implement a comprehensive, ongoing IRM education program designed to convey to COT102 x MON 15985 cotton users the importance of complying with the IRM program. The program shall include information encouraging COT102 x MON 15985 cotton users to pursue optional elements of the IRM program relating to refuge configuration and proximity to COT102 x MON 15985 cotton fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. Copies of the materials, including the Grower Guide or other technical bulletins, must be made available to EPA within 90 days of request. The program shall involve at least one written communication annually to each COT102 x MON 15985 cotton grower separate from the grower agreement. Monsanto Company shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.
- 2) Annually, Monsanto Company shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficient.
- 3) Within 90 days of request Monsanto Company shall provide a report to EPA summarizing the activities it carried out under its education program for the prior year and its plans for its education program during the current year.
- 4) Monsanto Company shall continue to implement an ongoing IRM compliance assurance program in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler. The program is designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the *Bt* cotton product. Other required features of the program are described in paragraphs 5 - 12 below.
- 5) Monsanto Company shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Monsanto Company will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase COT102 x MON 15985 cotton for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.
- 6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of COT102 x MON 15985 cotton growers conducted by an

independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Monsanto Company shall provide a written summary of the results of the prior year's survey to EPA by January 31st of each year, beginning in 2015. Monsanto Company shall confer with EPA on the design and content of the survey prior to its implementation.

- 7) Annually, Monsanto Company shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6, and from other sources. The changes shall address aspects of grower compliance that are not sufficient. Monsanto Company will confer with the Agency prior to adopting any changes.
- 8) Monsanto Company must conduct an annual on-farm assessment program. Monsanto Company shall train its representatives who make on-farm visits with COT102 x MON 15985 cotton growers to perform assessments of compliance with IRM requirements. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Monsanto Company shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 9) Monsanto Company shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto Company shall take appropriate action, consistent with its "phased compliance approach."
- 10) If a grower, who purchases COT102 x MON 15985 cotton for planting, was specifically identified as not being in compliance during the previous year, Monsanto Company shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.
- 11) By January 31, 2015 and annually thereafter, Monsanto Company shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Monsanto Company, and the results of these visits, the number of tips investigated, the percent of growers not in compliance with each refuge option (both size and distance), and the follow-up actions taken.
- 12) Monsanto Company must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

e. Insect Resistance Monitoring

Monsanto Company must carry out appropriate programs to detect the emergence of insect

resistance as early as possible. Resistance monitoring programs include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. Monsanto Company should coordinate its monitoring efforts for COT102 x MON 15985 with the current resistance monitoring programs for other registered *Bt* cotton products. For COT102 x MON 15985 cotton, the Agency imposes the following:

- 1) Monsanto Company must continue to develop and ensure the implementation of a plan for resistance monitoring for *Heliothis virescens* (tobacco budworm), *Helicoverpa zea* (cotton bollworm), and *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of tobacco budworm, cotton bollworm and pink bollworm populations to Cry1Ac, Cry2Ab2 and VIP3Aa19 proteins. Collection sites must be focused in areas of high adoption, with the goal of including all states where these insects are economic pests.
- 2) The following testing scheme for survivors of the diagnostic or discriminating concentrations (or identified survivors of any resistance detection method) must be implemented: 1) Determine if the observed effect is heritable; 2) Determine if the increased tolerance can be observed in the field (i.e., survive on COT102 x MON 15985 cotton plants); 3) Determine if the effect is due to resistance, 4) Determine the nature of resistance (dominant, recessive), 5) Determine the resistance allele frequency, 6) Determine, in subsequent years, whether the resistance allele frequency is increasing, and 7) Determine the geographic extent of the resistance allele (or alleles) distribution. Should the resistance allele frequency be increasing and spreading, a specific remedial action plan should be designed to mitigate the extent of *Bt* resistance. See section f. ("Remedial Action Plans") below.
- 3) Monsanto Company must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, black cutworm, fall armyworm, southern armyworm, and European corn borer. Monsanto Company will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Monsanto Company will investigate all damage reports. See Remedial Action Plans section below.
- 4) Monsanto Company must provide to EPA for review and approval any revisions to the tobacco budworm, cotton bollworm, and pink bollworm resistance monitoring plans prior to their implementation.
- 5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31<sup>st</sup> each year for pink bollworm.

f. Remedial Action Plans

Specific remedial action plans are required for COT102 x MON 15985 cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial Action Plan for Pink Bollworm

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Monsanto Company must implement the Arizona Bt Cotton Working Group's Remedial Action Plan. Monsanto Company must obtain approval from EPA before modifying the Arizona Bt Cotton Working Group's Remedial Action Strategy. The Arizona Bt Cotton Working Group's Remedial Action Plan can be found in Enclosure 1.

2) Remedial Action Plan for Tobacco Budworm and Cotton Bollworm

If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Monsanto Company must implement a Remedial Action Plan approved by EPA. Monsanto Company must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

**III. Reports**

The reporting requirements for COT102 x MON 15985 cotton are as follows:

- a. Annual Sales reported and summed by state (county level data available by request), submitted to EPA within 90 days of request;
- b. Grower Agreements number of units of Bt cotton seeds shipped or sold and not returned and the number of such units that were sold to persons who have signed grower agreements, submitted to EPA within 90 days of request;
- c. Grower Education substantive changes to education program completed previous year, submitted to EPA within 90 days of request;
- d. Compliance Assurance Program activities and results, January 31<sup>st</sup> each year, beginning in 2015;
- e. Compliance Survey Results to include annual survey results and plans for the next year full report January 31<sup>st</sup> each year, beginning in 2015;
- f. Insect Resistance Monitoring results of monitoring and investigations of damage reports, by June 30<sup>th</sup> each year for tobacco budworm and cotton bollworm and by December 31<sup>st</sup> each year for pink bollworm, beginning in 2015;

Submit two (2) copies of the revised final printed labeling before releasing the product for

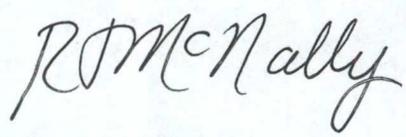
10/13

shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

Failure to comply with these terms will subject the registration to cancellation, in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these terms

A stamped copy of the label is enclosed for your records.

Sincerely,



Robert McNally  
Director  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosures (3)

11/23

**Plant-Incorporated Protectant Label**

**COT102 × MON 15985**

**Insect-Protected Cotton**

(Althornate Brand Name: Bollgard® III)

(OECD Unique Identifier SYN-IR102-7 × MON-15985-7)

**Active Ingredients:**

*Bacillus thuringiensis* Vip3Aa19 protein and the genetic material necessary (vector pCOT1) for its production in event COT102 cotton (OECD Unique Identifier SYN-IR102-7).....≤ 0.00051%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary (vector PV-GHBK11) for its production in event MON 15985 cotton (OECD Unique Identifier MON-15985-7) .....≤ 0.0540%\*

*Bacillus thuringiensis* Cry1Ac protein and the genetic material necessary (vector PV-GHBK04) for its production in event MON 15985 cotton (OECD Unique Identifier MON-15985-7) .....≤ 0.00059%\*

**Other Ingredients:**

Hygromycin B phosphotransferase (APH4), marker protein, and the genetic material necessary (vector pCOT1) for its production in event COT102 cotton (OECD Unique Identifier SYN-IR102-7) .....≤ 0.00007%\*

Neomycin phosphotransferase II (NPTII), marker protein, and the genetic material necessary (vector PV-GHBK04) for its production in event MON 15985 cotton (OECD Unique Identifier MON-15985-7) .....≤ 0.00061%\*

β-glucuronidase protein (GUS), marker protein, and the genetic material necessary (vector PV-GHBK11) for its production in event MON 15985 cotton (OECD Unique Identifier MON-15985-7) .....≤ 0.0066%\*

\* Percentage (wt/wt) on a dry weight basis.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

Net (Contents) \_\_\_\_\_

**ACCEPTED**

FEB 20 2014

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-613

® Bollgard III is a registered trademark of Monsanto Technology LLC.

Transformed cotton must be accompanied by the Grower Guide, which contains the following information:

1. The *B.t.* proteins expressed in this cotton control the above listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.* proteins is planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production, and insect-resistance management.
4. Bollgard III must not be planted nor sold for commercial planting in Hawaii, Puerto Rico, U.S. Virgin Islands, and south of Route 60 (near Tampa) in Florida.

The following information regarding test plots and seed production must be displayed on bags/bag tags of Bollgard III cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within three miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard III cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within three miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

In the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler, all growers of Bollgard III cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) are planted for every 95 acres of Bollgard III (total of 100 acres). The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of

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In the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler, all growers of Bollgard III cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) are planted for every 95 acres of Bollgard III (total of 100 acres). The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. At the pre-squaring cotton stage only, the refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lb of active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard III, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to Bollgard III. Ensure that a non-*Bt* cotton refuge is maintained within at least 1/2 linear mile (preferably adjacent to or within 1/4 mile or closer) from the Bollgard III fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton (refuge cotton) are planted for every 80 acres of Bollgard III (total of 100 acres). The variety of cotton planted in the refuge must be comparable to Bollgard III especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to Bollgard III. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Bt* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within 1/2 mile or closer) from the Bollgard III cotton fields.

3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of Bollgard III. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Bt* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the Bollgard III cotton. There is no field unit option.